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510(k) Safety and Effectiveness Summary

Submitter: Oncology Data Systems, Inc.
12401 Riverview Rd.
Oklahoma City, Ok. 73173
tel. (405) 691-2770
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Contact: Gregory G. Miller

Date: July 13, 2001

Trade Name: muCheck - Monitor Unit Validation Program

Common Name: Monitor Unit Validation Program

Classification Panel: Radiology

Classification Name: Medical Charged Particle Radiation Therapy System(Accessory)
21 CFR 892.5050 (class II)

Performance Standards: none established under section 514

Substantial Equivalence: mucheck – Monitor Unit Validation(K980904)
RadCalc (K010464)

Description:
The muCheck Monitor Unit Validation Program is a software program that is designed to operate on an IBM compatible personal computer in a Windows environment. It has been designed to operate on a stand alone mode independent of any radiation treatment planning system. It does not connect to or control any radiation hardware device. MuCheck performs monitor unit and dose calculations to verify the monitor unit and dose calculated by the primary radiation treatment planning system.

Substantial Equivalence Summary:

Intended Use:
The intended use for the muCheck - Monitor Unit Validation Program is the same as for the predicate devices: to calculate a monitor unit or dose for the purpose of validating a monitor unit or dose previously calculated by a primary radiation treatment planning system or hand calculation. The intended use is as a quality assurance tool only and not as a treatment planning device.

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In a radiation therapy department quality assurance is an important part of patient care. The ability to provide a secondary check for the primary monitor unit calculation is part of good treatment protocol as well being a recommendation by Task Group 40. Mucheck provides this very important quality assurance function.

Safety and Effectiveness:
The staff at Oncology Data Systems includes a certified medical dosimetrist with over 23 years of clinical experience. The computer programming and design has been provided by a systems analyst with over 23 years of experience in the design and development of systems. The combined expertise as well as conformance to the GMP regulations helped to insure that the finished product is safe and effective to use.

A comprehensive users manual available as a hard copy as well as on-line, provides extensive documentation for the user. Initial system startup and training is provided as part of the service provided by Oncology Data Systems.

Technological Characteristics:
The technological characteristics are the same as for the predicate devices. MuCheck was designed to operate in a windows environment using both mouse and keyboard.

Non-clinical tests:
Verification and validation test plans were completed in accordance with Oncology Data Systems procedures and GMP guidelines. A Hazard Analysis was completed and hazards were resolved as appropriate. All system specifications were met and testing performed to demonstrate substantial equivalence. The non-clinical tests were conducted using a treatment planning system or hand calculations and muCheck. The test results all matched very closely which supports the claim of substantial equivalence. See Figure 6.0 in section 6 for comparison summary.

Summary of Clinical Testing:
Clinical testing was not required to demonstrate substantial equivalence or safety and effectiveness.

Conclusions:
Based upon the technological characteristics, intended use, and non-clinical tests, muCheck is substantially equivalent to the predicate device. The documentation submitted for review supports this claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Mr. Gregory Miller
President
Oncology Data System, Inc.
12401 S. Riverview Road
OKLAHOMA CITY OK 73173

Re: K012227
Trade/Device Name: muCheck-Monitor Unit Validation Program
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: II
Product Code: 90 IYE
Dated: July 13, 2001
Received: July 16, 2001

Dear Mr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012227

Device Name: muCheck - Monitor Unit Validation Program

Indications For Use:

The **muCheck - Monitor Unit Validation Program** (the device under review) verifies the monitor unit or dose calculated by the primary treatment planning system. It serves as quality assurance as part of good treatment protocol to have a second means to verify the accuracy of the primary calculation.

The Intensity Modulated Radiotherapy and Diode corrections features added to the software extends the use of the program to verify dose calculations performed by the primary treatment planning system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012227

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)